F.H. 09/053,108
abandoned

United States Patent File History

Tab Listings

A. References (if applicable)
- **A1**–U.S. References
- **A2**–Foreign References

B. Jacket (face of file, contents flap, index of claims, PTO 270, searched)

C. Printed Patent

D. Specification (serial no. Sheet, abstract, specification, claims)

E. Oath
- **E1**–Small Entity Status (if applicable)

F. Drawing Figures (if applicable)

G. USPTO/Applicant Correspondence

H. Original Patent Application (in cases of FWC)

ISSUE CLASSIFICATION	Class	Subclass

PATENT NUMBER

U.S. UTILITY PATENT APPLICATION

O.I.P.E.	PATENT DATE
SCANNED MN on Drwl	

SECTOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
	606	534	3751	R.E.P

FILED WITH: ☐ DISK (CRF) ☐ FICHE
(Attached in pocket on right inside flap)

ABANDONED

PREPARED AND APPROVED FOR ISSUE

ISSUING CLASSIFICATION

ORIGINAL		CROSS REFERENCE(S)	
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)
INTERNATIONAL CLASSIFICATION			
			☐ Continued on Issue Slip Inside File Jacket

☐ TERMINAL DISCLAIMER	DRAWINGS			CLAIMS ALLOWED	
	Sheets Drwg.	Figs. Drwg.	Print Fig.	Total Claims	Print Claim for O.G.

☐ a) The term of this patent subsequent to _____ (date) has been disclaimed.	_____ (Assistant Examiner) _____ (Date)	NOTICE OF ALLOWANCE MAILED
☐ b) The term of this patent shall not extend beyond the expiration date of U.S Patent. No. _____	_____ (Primary Examiner) _____ (Date)	ISSUE FEE: Amount Due / Date Paid
☐ c) The terminal ___months of this patent have been disclaimed.	_____ (Legal Instruments Examiner) _____ (Date)	ISSUE BATCH NUMBER

Form PTO-436A
(Rev. 10/97)

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ISSUE SLIP STAPLE AREA (for additional cross references)

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POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION	BA	70385	
O.I.P.E. CLASSIFIER		21	4/6/95
FORMALITY REVIEW		7021	3/4/99

INDEX OF CLAIMS

✔ ..... Rejected
= ..... Allowed
— (Through numeral) Canceled
÷ ..... Restricted
N ..... Non-elected
I ..... Interference
A ..... Appeal
O ..... Objected

Claim Final	Claim Original	Date 4/6/99
	(1)	✓
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	7	✓
	8	✓
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If more than 150 claims or 10 actions staple additional sheet here

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SEARCHED

Class	Sub.	Date	Exmr.
606	92	4/7/99	DR
	93		
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604	207		
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SEARCH NOTES
(INCLUDING SEARCH STRATEGY)

	Date	Exmr.
APS SEARCH	4/7/99	DR

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.

(RIGHT OUTSIDE)

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/053,108	04/01/98	606	3731	361722000300

APPLICANT: HOWARD PREISSMAN, SAN JOSE, CA.

CONTINUING DOMESTIC DATA********
VERIFIED

DR — NONE —

371 (NAT'L STAGE) DATA********
VERIFIED

DR — NONE —

FOREIGN APPLICATIONS********
VERIFIED

DR — NONE —

FOREIGN FILING LICENSE GRANTED 05/04/98 ***** SMALL ENTITY *****

Foreign Priority claimed 35 USC 119 (a-d) conditions met / Verified and Acknowledged	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐yes ☒no ☐yes ☐no ☐Met after Allowance; Examiner's Initi: DR; Initials:	CA	8	30	4

ALAN W. CANNON
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755 PAGE MILL ROAD
PALO ALTO CA 94304-1018

PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT

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FILING FEE RECEIVED	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit
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Jc564 U.S. PTO
09/053108
04/01/98

PATENT APPLICATION

09053108

INITIALS ________

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ABANDONED

No.	Contents	Date received (Incl. C. of M.) or Date Mailed
1.	Application ________ papers.	
2.	Fees unsigned dec	5/5/98
3.	Dec./Fee/Surcharge	7/6/98
4.	Sm Entity	7/6/98
5.	IDS	7/6/98
6.	NE 3 mos	4-13-99
7.	ABN	10-18-99
8.	Request for Access	3/18/02
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PTO/SB/05 (12/97) (modified)
Approved for use through 09/30/00. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	361722000300	Total Pages	32
First Named Inventor or Application Identifier			
Howard Preissman			
Express Mail Label No.	EM216129969US		

JC494 U.S. PTO 04/01/98

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Express Mail Label No.: EM216129969US Date of Deposit: April 1, 1998

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Sheri A. Wysocki

Sheri A. Wysocki

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. [X] Fee Transmittal Form *(Submit an original, and a duplicate for fee processing)*
2. [X] Specification [Total Pages 20] *(preferred arrangement set forth below)*
   - Descriptive title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. [X] Drawing(s) *(35 USC 113)* [Total Sheets 8]
4. Oath or Declaration [Total Pages 2]
   a. [ ] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional with Box 17 completed)* *[Note Box 5 below]*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b)
5. [ ] Incorporation By Reference *(useable if Box 4b is checked)* The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. [ ] Microfiche Computer Program *(Appendix)*
7. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Copy
   b. [ ] Paper Copy (identical to computer copy)
   c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. [ ] Assignment Papers (cover sheet & document(s))
9. [ ] 37 CFR 3.73(b) Statement [ ] Power of Attorney *(when there is an assignee)*
10. [ ] English Translation Document *(if applicable)*
11. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
12. [ ] Preliminary Amendment
13. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
14. [ ] Small Entity Statement(s) [ ] Statement filed in prior application, Status still proper and desired
15. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. [ ] .....

17. If a CONTINUING APPLICATION, *check appropriate box and supply the requisite information:*
[ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No:

18. CORRESPONDENCE ADDRESS

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☒ If a paper is untimely filed in the above-referenced application by applicant or his/her representative, the Assistant Commissioner is hereby petitioned under 37 C.F.R. § 1.136(a) for the minimum extension of time required to make said paper timely. In the event a petition for extension of time is made under the provisions of this paragraph, the Assistant Commissioner is hereby requested to charge any fee required under 37 C.F.R. § 1.17(a)-(d) to **Deposit Account No. 03-1952.** However, the Assistant Commissioner is **NOT** authorized to charge the cost of the issue fee to the Deposit Account.

The filing fee has been calculated as follows:

FOR	NUMBER FILED	NUMBER EXTRA	RATE	CALCULATIONS
TOTAL CLAIMS	30 - 20 =	10	x $22.00	$220.00
INDEPENDENT CLAIMS	4 - 3 =	1	x $82.00	$82.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $270.00	$0.00
			BASIC FEE	$790.00
		TOTAL OF ABOVE CALCULATIONS =		$1,092.00
Reduction by 1/2 for filing by small entity (Note 37 C.F.R. §§ 1.9, 1.27, 1.28). If applicable, verified statement must be attached.				$546.00
Assignment Recording Fee (if enclosed)				$0.00
			TOTAL =	$546.00

Dated: April 1, 1998

Respectfully submitted,

By: [signature]
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Docket No. 361722000300

pa-261353

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

PTO-1556
(5/87)

PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is related to copending application serial no. 08/950,382, filed on October 14, 1997, which is hereby incorporated by reference thereto in its entirety.

TECHNICAL FIELD

The present invention relates to instruments for more accurately controlling the placement thereof, during surgical procedures for the repair of hard tissue by injection of hard tissue implant materials. Procedures for such repair include hip augmentation, mandible augmentation, and particularly vertebroplasty, among others.

BACKGROUND ART

Polymethylmethacrylate (PMMA) has been used in anterior and posterior stabilization of the spine for metastatic disease, as described by Sundaresan et al., "Treatment of neoplastic epidural cord compression by vertebral body resection and stabilization." *J Neurosurg* 1985;63:676-684; Harrington, "Anterior decompression and stabilization of the spine as a treatment for vertebral collapse and spinal cord compression from metastatic malignancy." *Clinical Orthodpaedics and Related Research* 1988;233:177-197; and Cybulski, "Methods of surgical stabilization for metastatic disease of the spine." *Neurosurgery* 1989;25:240-252.

Deramond et al., "Percutaneous vertebroplasty with methyl-methacrylate: technique, method, results [abstract]." *Radiology* 1990;117 (suppl):352; among others, have described the percutaneous injection of PMMA into vertebral compression fractures by the transpedicular or paravertebral approach under CT and/or fluoroscopic guidance. Percutaneous vertebroplasty is desirable from the

standpoint that it is minimally invasive, compared to the alternative of surgically exposing the hard tissue site to be supplemented with PMMA or other filler.

The general procedure for performing percutaneous vertebroplasty involves the use of a standard 11 gauge Jamshidi needle. The needle includes an 11 gauge cannula with an internal stylet. The cannula and stylet are used in conjunction to pierce the cutaneous layers of a patient above the hard tissue to be supplemented, then to penetrate the hard cortical bone of the vertebra, and finally to traverse into the softer cancellous bone underlying the cortical bone.

A large force must be applied by the user, axially through the Jamshidi needle to drive the stylet through the cortical bone. Once penetration of the cortical bone is achieved, additional downward axial force, but at a reduced magnitude compared to that required to penetrate the cortical bone, is required to position the stylet/ tip of the cannula into the required position within the cancellous bone. When positioned in the cancellous bone, the stylet is then removed leaving the cannula in the appropriate position for delivery of a hard tissue implant material to reinforce and solidify the damaged hard tissue.

A syringe is next loaded with polymethyl methacrylate (PMMA) and connected to the end of the cannula that is external of the patient's body. Pressure is applied to the plunger of the syringe to deliver the PMMA to the site of damaged bone at the distal end of the cannula. Because in general, 10cc syringes are only capable of generating pressures of about 100-150 psi, this places a limitation on the viscosity of the PMMA that can be effectively "pushed through" the syringe and cannula and fully delivered to the implant site. Of course, the use of a small barrel syringe, e.g., a 1 cc syringe enables the user to generate higher driving pressures. For example pressures of 1000 psi and possibly as high as 1200-1500 psi (depending upon the strength of the user and the technique) may be generated using a 1 cc syringe. A serious limitation with the use of a 1 cc syringe, however, is that it will not hold a large enough volume to complete the procedure in one step or "load" and

must be reloaded several times to complete the procedure, since, on average, about 3.5 cc of implant material per side of the vertebral body are required for an implantion procedure. This makes the procedure more complicated with more steps, and more risky in that the polymerization of the implant material causes it to become increasingly more viscous during the additional time required for reloading. Another problem with a 1 cc syringe is lack of control, as high pressures are generated in a "spike -like" response time and are not continuously controllable.

A viscous or paste-like consistency of PMMA is generally believed to be most advantageous for performing percutaneous vertebroplasty. Such a consistency insures that the implant material stays in place much better than a less viscous, more liquid material. Additionally, when PMMA is implanted percutaneously, the need to inject it through a relatively narrow needle or cannula also greatly increases the need for a high pressure driver. Still further, implantation of PMMA into a relatively closed implantation site (e.g., trabecular bone) further increases the resistance to flow of the PMMA, at the same time increasing the pressure requirements of the driver. Thus, there is a need for a high pressure applicator that has enough storage capacity to perform a complete implantation procedure without having to reload the device in the midst of the procedure, and which is consistently controllable, for an even, constant application of pressure during delivery of the entirety of the implant material.

Leakage or seepage of PMMA from the vertebral implant site can cause a host of complications some of which can be very serious and even result in death. For example, Weil et al. reported cases of sciatica and difficulty in swallowing which were related to focal cement leakage, *Radiology* 1996;Vol 199, No. 1, 241-247. A leak toward the distal veins poses an even more serious risk, since this can cause a pulmonary embolism which is often fatal.

Attempts have been made to increase the ability to apply pressure to drive PMMA to the vertebral implant site by providing a smaller barrel syringe, but this

holds less volume and must be refilled once or several times to deliver enough volume of PMMA to the site. Since there is a limited amount of time to work with PMMA before it begins to polymerize or set up, this type of procedure is more difficult to successfully complete within the allotted time, and thus poses an additional risk to the success of the operation.

Accordingly, there exists a need for an improved apparatus and procedure for controllably applying higher pressures to a source of hard tissue implant material to successfully implant the material at the desired location in a single batch, for the performance of vertebroplasty and particularly, percutaneous vertebroplasty.

DISCLOSURE OF THE INVENTION

Disclosed is a high pressure applicator for driving the delivery of a hard tissue implant material. In a preferred embodiment, the applicator includes an exteriorly threaded column for receiving and containing a hard tissue implant material. The exteriorly threaded column is open at one end and is provided with a transfer fitting at the other end. An interiorly threaded column is provided which is mateable with the exterior threads on the exteriorly threaded column. The interiorly threaded column is open at one end and closed at the other end.

A stabilizer is fixedly attached to the exteriorly threaded column and radially extends therefrom to provide a user a mechanical advantage upon grasping, which prevents the exteriorly threaded column from rotating during rotation of the interiorly threaded column. A handle is fixed to and extends radially from the internally threaded column to provide the user a mechanical advantage upon grasping, thereby increasing a maximum torque that can be applied to the interiorly threaded column.

The high pressure applicator is capable of controllably generating pressures of up to about 3000 psi for driving hard tissue implant materials. The transfer fitting preferably comprises a luer lock.

The high pressure applicator according to the present invention includes a chamber for receiving a volume of the hard tissue implant material that is sufficient to complete an implantation procedure without the need to refill the chamber during the implantation procedure. Means for manually applying pressure to the chamber are provided and are capable of applying controllable pressures of up to about 3000 psi to the chamber. A stabilizer is fixedly attached to at least a portion of the chamber and radially extends therefrom to provide a user a mechanical advantage upon grasping.

A method of implantation of a hard tissue implant material is disclosed to include inserting a delivery tube into a hard tissue site where implantation of a hard tissue implant material is desired; connecting a high pressure applicator containing a predetermined volume of hard tissue implant material to the delivery tube; and applying a high pressure to the hard tissue implant material with the high pressure applicator, to drive the hard tissue implant material through the delivery tube and into the site.

The application of high pressure to the hard tissue implant material is preferably performed at a pressure of at least about 1000 psi. The high pressure application can be applied within a pressure range of about 1000 to 2000 psi, and up to about 3000 psi.

The insertion of the delivery tube into the hard tissue site further includes inserting a stylet into the site where implantation of a hard tissue implant material is desired; and guiding the delivery tube over the stylet into the site where implantation of a hard tissue implant material is desired. Further, the stylet is removed from within the delivery tube prior to connecting the high pressure applicator to the delivery tube.

The insertion of the delivery tube into the hard tissue site is preferably monitored using an imaging device, which preferably includes a fluoroscopic device. Additionally, the viewing the delivery of hard tissue implant material into the site is preferably monitored using an imaging device, preferably a fluoroscopic device,

wherein the application of a high pressure is controlled according to feedback observed from the viewing.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a diagram of an initial phase of insertion of a stylet into an implant site;

Figure 2 shows the stylet having penetrated the cortical bone and approaching cancellous bone;

Figure 3 shows the stylet having reached the desired site of implantation;

Figure 4 illustrates the positioning of a cannula by guiding it along the stylet;

Figure 5 is a view of the cannula in position at the desired site of implantation, with the stylet still in position;

Figure 6 is a view after the stylet has been removed and the high pressure applicator has been mounted to the cannula;

Figure 7 is a view of high pressure applicator after being loaded with a hard tissue implant material and assembled;

Figure 8 is an alternative embodiment of what is shown in Figure 6; and

Figure 9 is a view of the high pressure applicator used in the embodiment of Figure 8.

BEST MODE FOR CARRYING OUT THE INVENTION

The present invention substantially improves the delivery of hard tissue implant sites to the targeted zone of implantation, and is especially well suited for percutaneous deliveries. The present invention substantially reduces several of the risk factors associated with the performance of percutaneous vertebroplasty. Additionally, the present invention enables an increase in an upper acceptable viscosity value of the implant to be delivered because of the increase in the amount of pressure available for controllably driving the delivery.

An example of a procedure for performing percutaneous vertebroplasty is illustrated in Figures 1-6 . A stylet 1 is provided which has a length that is more than sufficient to span the distance from the epidermis of a patient to the cancellous bone tissue in the vertebra, in the preferred configuration. Typically the length of the stylet would be about three inches or greater, but lesser lengths may also be employed as well, depending on the size of the patient. Of course, if other hard tissues are to be accessed, the length of the stylet can be readily modified without departing from the inventive features of the present invention.

The stylet 1 is preferably made of a surgical grade of stainless steel, but other known equivalent biocompatible metals and materials may be used for the same purpose. Ideally, the stylet, or at least a distal end thereof, will be radiopaque so that it can be monitored using fluoroscopy, CT or other imaging techniques during the procedure to help determine the depth and location of the penetration.

A first or distal end of the stylet 1 ends in a point 2 which is sharp and adapted to penetrate hard tissue when axially loaded. Extending from the tip 2 in the example shown in Figure 1 are self-tapping threads 4. However, other procedures may employ a stylet which does not have self tapping threads, but rather, is simply forced into the implantation site so that the point 2 pierces a pathway to the site of implantation. The self-tapping threads 4 provide an advantage in that once the tip 2 has penetrated the cortical bone (e.g., see Figure 2), the operator of the stylet can than proceed to advance the stylet by torquing the stylet, which engages the self-tapping threads 4 in the cortical bone 103 and begins to screw the stylet 1 into the cortical bone 103, as illustrated in Figure 2.

Turning to Figure 1, a preferred example of depth guided instruments will now be described. A stylet 1 is provided which has a length that is more than sufficient to span the distance from the epidermis of a patient to the cancellous bone tissue in the vertebra, in the preferred configuration. Typically the length of the stylet would be about three inches or greater, but lesser lengths may also be employed as

well, depending on the size of the patient. Of course, if other hard tissues are to be accessed, the length of the stylet can be readily modified without departing from the inventive features of the present invention.

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A cannula 10 is provided which includes an elongated tubular structure 11 to be positioned in the cancellous bone or other implantation site for delivery of PMMA or other bone implant material therein. The tubular structure 11 of the cannula 10 is preferably made of a surgical grade of stainless steel, but may be made of known equivalent materials, similarly to the stylet 1 discussed above. Preferably, at least a distal end of the tubular structure is radiopaque. The tubular structure 11 has an inside diameter which is only slightly larger than the outside diameter of the stylet 1, so that the cannula may effortlessly pass axially over the stylet, while at the same

time being supported and guided by the stylet. A first or distal end 12 of the cannula is preferably (but not necessarily) beveled to ease the penetration of the cannula through the cutaneous and soft tissues, and especially through the hard tissues.

Surrounding the second end of the tubular structure 11 is a connector 18 (Figure 6) for linking the cannula 10 with a pressure applicator according to the present invention, for supplying the PMMA or other implantable material that is to be injected via tubular structure 11. Preferably, connector 18 is a Luer-lock type of connector, but other known connecting mechanisms may be successfully interchanged, e.g., a conventional threaded hole, a threads and locking nut arrangement, etc.

As shown in Figures 4-5, the cannula 10 is advanced over the stylet, until visualization of the process indicates that the end of the cannula 12 is substantially even with the tip of the stylet 2, whereby it is confirmed that the cannula is properly positioned for delivery of the implant material. Next the stylet 1 is removed from the site, either by reverse rotation or by simply withdrawing it. At the same time the cannula 10 is maintained in position to be readied for delivery of the implant material.

A pressure applicator 50 according to the present invention is next mounted to the connector 18 at the end of cannula 10, as shown in Figure 6. The pressure applicator 50 is provided with a fitting 52 which is designed to form a pressure tight connection with the connector 18. As mentioned above, the preferred type of connection is a Luer-lock type connection, but alternative, equivalent types of connectors may be employed. The pressure applicator further includes a first column 54 for receiving and containing the hard tissue implant material. The first column 54 is open at one end 54a for receiving the implant material. At the other end 54b of the first column is a much smaller opening which ends with the connector or transfer fitting 52.

A second column 56 is provided for overfilling first column 54 and providing a pressure seal therewith. Preferably, the second column is interiorly threaded 58 and the interior threads 58 mate with exterior threads 60 provided on the first column 54. However, other equivalent types of driving arrangements, e.g., a ratchet and pawl arrangement or other equivalent arrangements could be used in place of the mating threads, so long as adequate pressure is able to be generated and maintained between the two columns for providing the driving force for the implant material.

Column 56 is open at end 56a for receiving the first column 54 therein. At the opposite end 56b, column 56 is closed to enable a generation of pressure within the two columns as they are moved toward one another and column 56 passes over column 54. Preferably, at least one sealing element 57 (e.g., an O-ring) is provided in the interface between columns 54 and 56 to maintain a high pressure fitting therebetween.

A handle 62 is mounted on the column 56 to provide additional leverage for driving the column 56 with respect to column 54. In the example shown in Figure 6, the handle 62 is provided at the closed end 56b to provide a greater mechanical advantage for torquing column 56 about its longitudinal axis. Of course, the handle could be provided anywhere along the column 56 so long as it extends the effective radius for torquing about the longitudinal axis. For other types of driving mechanisms other types of handles might be employed. For example, a lever might extend from the column in an embodiment using a ratchet and pawl type of driving mechanism.

A stabilizer 64 is fixedly attached or mounted to the first column 54. The stabilizer 64 may be grasped by the operator and provides leverage against rotation of the first column 54 during driving of the second column 56. Preferably, the stabilizer 64 is in the form of a lever as shown in Figure 6, but alternative embodiments of the stabilizer may include a circular handle, etc. so long as an equal mechanical advantage is provided to the user.

The above described components of the pressure applicator 50 are all preferably formed of polycarbonate. However, any other materials which are durable, sterilizable and biofriendly, such as stainless steel, could be readily substituted.

Prior to mounting the pressure applicator 50 on the cannula 10, a hard tissue implant material 66 is loaded into the first column 54 and the second column 56 is connected with the first column 54 in preparation for implantation, see Figure 7. The first column is then rotated slightly with respect to the second column until a minimal amount of tissue implant material is expressed from the fitting 52 end, to ensure that no air has been entrapped in the applicator. The cannula 10 is backfilled with saline, tissue implant material 66, or other biocompatible fluid in order to displace the air therefrom. The pressure applicator 50 is then mounted onto the cannula 10 as described above and shown in Figure 6. The operator next grasps the handle 62 in one hand and the stabilizer 64 in the other and begins to torque the handle 62 while maintaining the stabilizer 64 in its position. When operated as described, the pressure applicator is capable of generating pressures of about 1000 to 2000 psi within the columns, which is a high driving force that is applied to the implantable material 66.

Torquing of the handle 62 with respect to the stabilizer 64 is continued until a sufficient amount of implant material 66 has been delivered to the implant site as verified by an appropriate imaging technique. Advantageously, the pressure applicator 50 allows a first column 54 which is large enough in volume to contain sufficient implant material for an entire implantation process so that there is no need to refill the column 54 in the midst of a procedure.

A modification of the apparatus described above is shown in Figure 8. In this embodiment, cannula 10' includes a modified tubular structure design. The first or distal portion 11a of the tubular structure is of the same dimensions as the embodiment of Figures 1-6. The second or proximal portion 11b of the cannula 10',

however, has a substantially larger diameter than that of the first portion 11a. Preferably, the diameter of second portion 11b is about twice the diameter of the first portion 11a, although any increase in the diameter of the second portion 11b over that of the first portion 11a will decrease the pressure requirement for effective delivery of the material to be implanted.

The first and second portions 11a,11b have approximately equal lengths, but this is governed by the anatomy of the site to be accessed. In the "average" percutaneous vertebroplasty situation, the first portion 11a is required to be about 1.5" long, as this is the length that is needed for traversing the cortical bone of the pedicle. Thus, the first portion should not be significantly enlarged due to the size constraints of the pedicle, the safety risks to the spinal column and aorta which are increased when the cannula size is increased intravertebrally, and by the desire to remove as little bone as possible when entering with the stylet and cannula, among other factors.

However, the portion of the cannula which will occupy the soft tissues can be significantly expanded without substantially adversely effecting the patient. Given the benefits of reducing the required injection pressure and ensuring a better delivery of the bone implant material, such a modification becomes a viable option.

The pressure applicator 50' is essentially the same as that in the previous embodiment, with modifications as follows. The pressure applicator 50' is provided with a fitting 52' which is designed to form a pressure tight connection with the connector 18' and is therefore of a significantly larger diameter than the connector 52. Additionally, the first column 54' is essentially open at both ends 54a' and 54b' as it does not taper or tapers much less than the previous embodiment at opening 54b'. As mentioned above, the preferred type of connection is a Luer-lock type connection, but alternative, equivalent types of connectors may be employed.

Like pressure applicator 50, the components of the pressure applicator 50' are all preferably formed of polycarbonate. However, any other materials which are

durable, sterilizable and biofriendly, such as stainless steel, could be readily substituted.

Prior to mounting the pressure applicator 50' on the cannula 10', a hard tissue implant material 66 is loaded into the first column 54 and the second column 56 is connected with the first column 54 in preparation for implantation. The pressure applicator 50' is then mounted onto the cannula 10' as shown in Figure 8. The operator next grasps the handle 62 in one hand and the stabilizer 64 in the other and begins to torque the handle 62 . When operated as described, the pressure applicator is capable of generating controllable and sustainable pressures of up to about 3000 psi within the columns, which is a high driving force that is applied to the implantable material 66.

Alternative to the direct connection of the pressure applicator 50 to the connector 18 via fitting 52, as shown in Figure 6, a high pressure tubing 70 may be and preferably is interconnected between the pressure applicator 50 and the cannula 10, as shown in Figure 10. Preferably, the tubing 70 is a braided, reinforced polyurethane tubing rated up to at least 1200 psi, although alternative, equivalently performing high pressure tubing may be substituted. The tubing 70 has male 72 and female 74 connectors for forming pressure tight seals with fitting 52 and connector 18, respectively.

The tubing 70 enables both the applicator 50, and thus the user's hand to be distanced from the radiographic field or other viewing field, which is advantageous both for safety purposes as well as improving the procedure. This embodiment is particularly advantageous for the most frequent set-ups where bi-planar viewing is performed and two imaging devices are oriented at 90° to one another about the implantation site. One of the advantages which is gained that improves the procedure, is that the viewing instrumentation can be moved closer to the actual implantation site, thereby providing a more magnified view.

It is preferred that the tubing 70 is mounted to the pressure applicator prior to mounting on the cannula fitting 18. After filling the pressure applicator with implant material as described above, the tubing 70 is mounted to fitting 52. A small amount of pressure is next applied to the implant material to express the implant material until a minimal amount exits the open end of the tubing (i.e., the end where connector 74 is located). The tubing 70 is then connected to the connector 18 of the cannula 10 for implantion of the implant material into the desired location. Although the foregoing is the desired order of connection so that the air space in the tubing can be prefilled with implant material, it is not the only possible progression for the procedure. Alternatively, the tubing 70 can be connected to the fitting 18 of the cannula 10 and the tubing 70 and cannula 10 are then backfilled with saline, implant material, or other biocompatible fluid to displace any air residing in the structures. After filling of the pressure applicator 50 with implant material, the tubing can be connected to the fitting 52 and implantion of the implant material can be rapidly commenced thereafter.

Although there have been described devices for percutaneous delivery of a hard tissue implant material, with a limited selected number of alternative embodiments in accordance with the invention for the purpose of illustrating the manner in which the invention may be used to advantage, it will be appreciated that the invention is not limited thereto. Accordingly, any and all modifications, variations or equivalent arrangements which may occur to those skilled in the art should be considered to be within the scope of the invention as set forth in the claims which follow.

CLAIMS

1. A high pressure applicator for driving the delivery of a hard tissue implant material, comprising:

an exteriorly threaded column for receiving and containing a hard tissue implant material, said exteriorly threaded column being open at one end and being provided with a transfer fitting at the other end;

an interiorly threaded column mateable with exterior threads on said exteriorly threaded column, said interiorly threaded column being open at one end and closed at the other end;

a stabilizer fixedly attached to said exteriorly threaded column and radially extending therefrom to provide a user a mechanical advantage upon grasping said stabilizer, thereby preventing said exteriorly threaded column from rotating during rotation of said interiorly threaded column.

2. The high pressure applicator of claim 1, further comprising:

a handle fixed to and extending radially from said internally threaded column to provide the user a mechanical advantage upon grasping said handle, thereby increasing a maximum torque that can be applied to said interiorly threaded column.

3. The high pressure applicator of claim 1, wherein said applicator is capable of generating pressures of up to about 3000 psi for driving hard tissue implant materials.

4. The high pressure applicator of claim 1, wherein said transfer fitting comprises a luer lock.

5. A high pressure applicator for driving the delivery of a hard tissue implant material, comprising:

a chamber for receiving a volume of the hard tissue implant material that is sufficient to complete an implantation procedure without the need to refill said chamber; and

means for manually applying pressure to said chamber, wherein said means for manually applying pressure are capable of applying pressures of at least 1000 psi to said chamber.

6. The high pressure applicator of claim 5, wherein said means for manually applying pressure are capable of applying pressures of up to about 2000 psi to said chamber.

7. The high pressure applicator of claim 5, wherein said means for manually applying pressure are capable of applying pressures of up to about 3000 psi to said chamber.

8. The high pressure chamber of claim 5, further comprising:

a stabilizer fixedly attached to at least a portion of said chamber and radially extending therefrom to provide a user a mechanical advantage upon grasping said stabilizer.

9. A method of implantation of a hard tissue implant material, comprising:

inserting a delivery tube into a hard tissue site where implantation of a hard tissue implant material is desired;

connecting a high pressure applicator containing a predetermined volume of hard tissue implant material to said delivery tube;

applying a high pressure to the hard tissue implant material with said high pressure applicator, to drive the hard tissue implant material through said delivery tube and into the site.

10. The method of claim 9, wherein said applying a high pressure comprises applying a pressure of at least about 1000 psi.

11. The method of claim 10, wherein said applying a high pressure comprises applying a pressure of about 1000 to 2000 psi.

12. The method of claim 10, wherein said applying a high pressure comprises applying a pressure of up to about 3000 psi.

13. The method of claim 9, wherein said inserting a delivery tube into a hard tissue site comprises:

inserting a stylet into the site where implantation of a hard tissue implant material is desired; and

guiding said delivery tube over said stylet into the site where implantation of a hard tissue implant material is desired.

14. The method of claim 13, further comprising:

removing said stylet from within said delivery tube prior to said connecting a high pressure applicator containing a predetermined volume of hard tissue implant material to said delivery tube.

15. The method of claim 9, further comprising:

viewing the insertion of said delivery tube into the hard tissue site using an imaging device.

16. The method of claim 15, wherein said imaging device comprises a fluoroscopic device.

17. The method of claim 9, further comprising:

viewing the delivery of hard tissue implant material into the site using an imaging device, wherein said application of a high pressure is controlled according to feedback observed from said viewing.

18. The method of claim 17, wherein said imaging device comprises a fluoroscopic device.

19. The method of claim 9, wherein said connecting said high pressure applicator to said delivery tube comprises connecting said high pressure applicator directly to said delivery tube.

20. The method of claim 9, wherein said connecting said high pressure applicator to said delivery tube comprises connecting said high pressure applicator to

a high pressure tube and in turn connecting said high pressure tube directly to said delivery tube.

21. The method of claim 9, wherein said connecting said high pressure applicator to said delivery tube comprises connecting said high pressure applicator to a high pressure tube which has been connected to said delivery tube.

22. A system for implantation of hard tissue material comprising:

a high pressure applicator for driving a delivery of the hard tissue implant material;

a delivery tube for insertion into a hard tissue site of implantation; and

means for interconnecting said high pressure applicator and said delivery tube.

23. The system of claim 22, wherein said means for interconnecting comprises interfitting Luer lock connectors on said high pressure applicator and said delivery tube, respectively.

24. The system of claim 22, wherein said means for interconnecting comprises:

a first pressure fitting on said delivery tube;

a second pressure fitting on said high pressure applicator; and

a portion of high pressure tubing interconnectable between said first and second pressure fittings.

25. The system of claim 22, further comprising a stylet which is insertable into said hard tissue implantation site to guide said insertion of said delivery tube.

26. The system of claim 22, wherein said high pressure applicator comprises a reservoir for containing the hard tissue implant material prior to implantation.

27. The system of claim 26, wherein said reservoir is capable of containing at least 7 cc of the hard tissue implant material.

28. The system of claim 26, wherein said reservoir is at least partially defined by a pair of interfitting cylindrical portions of said high pressure applicator.

29. The system of claim 22, wherein said high pressure applicator further comprises a stabilizer fixedly attached thereto and extending therefrom to provide a user a mechanical advantage upon grasping said stabilizer.

30. The system of claim 22, wherein said applicator is capable of generating pressures of up to about 3000 psi for driving the hard tissue implant material.

ABSTRACT OF THE DISCLOSURE

A pressure applicator for applying pressure to a slurry of bone implant material, e.g., PMMA. A pressure applicator or driver includes a column which is provided with threads on the exterior thereof for mating with internal threads of a handle. A stabilizer handle is provided for the operator to grasp and steady the device as he turns the handle to apply pressure to the PMMA within the column. A luer-lock or other connecting device is provided for attaching the driver to the cannula that will deliver the bone implant material to the desired site. Pressures of about 1000-2000 psi are expected to be generated by this device.

PATENT
Docket No. 361722000300

DECLARATION FOR UTILITY PATENT APPLICATION

AS A BELOW-NAMED INVENTOR, I HEREBY DECLARE THAT:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT, the specification of which is attached hereto unless the following box is checked:

☐ was filed on Herewith as United States Application Serial No. or PCT International Application No. Not Yet Assigned and was amended on * (if applicable).

I HEREBY STATE THAT I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE.

I acknowledge the duty to disclose information which is material to the patentability as defined in 37 C.F.R. § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed:

Application No.	Country	Date of filing (day/month/year)	Priority Claimed?
			☐Yes ☐No

I hereby claim benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application Serial No.	Filing Date

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to

patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

Application Serial No.	Filing Date	Status
		☐Patented ☐Pending ☐Abandoned

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date

Name: Howard Preissman
Residence: 2140 Jonathan Avenue, San Jose, California 95125
Citizenship: USA
Post Office Address: Same as Residence

606/53

3751
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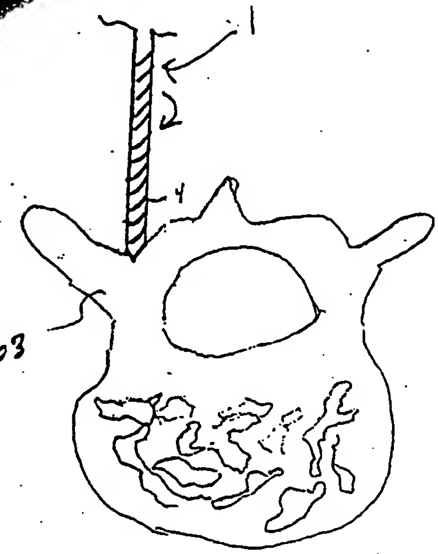

Fig 1

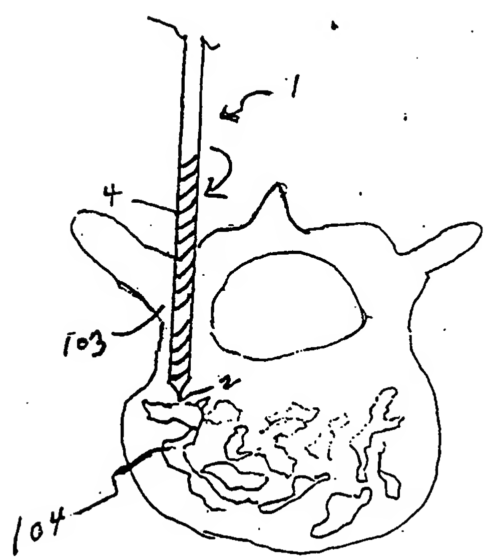

Fig 2

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AS ORIGINALLY FI

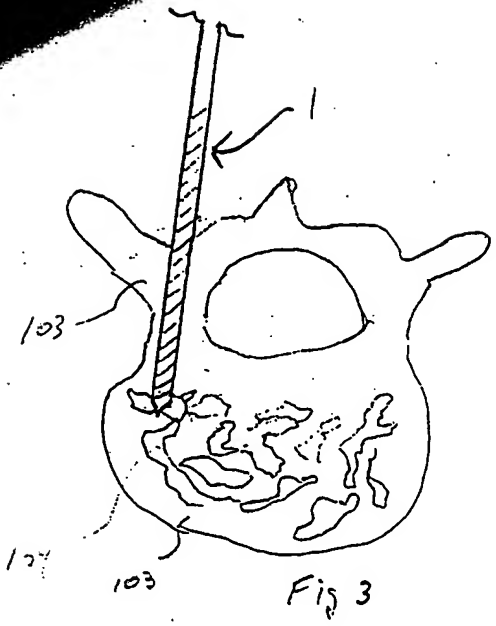

Fig 3

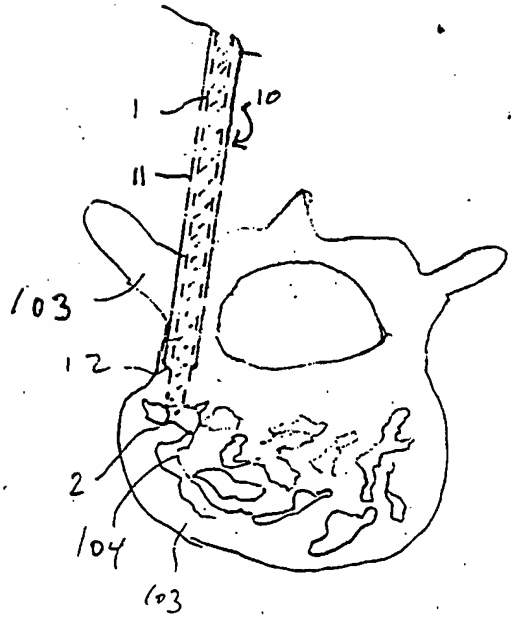

Fig. 4

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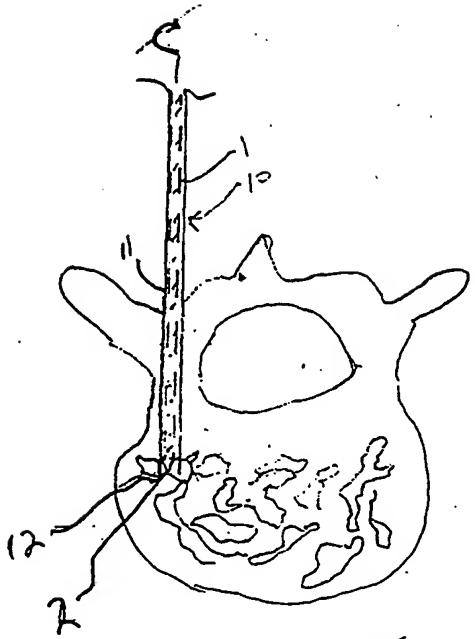

Fig. 5

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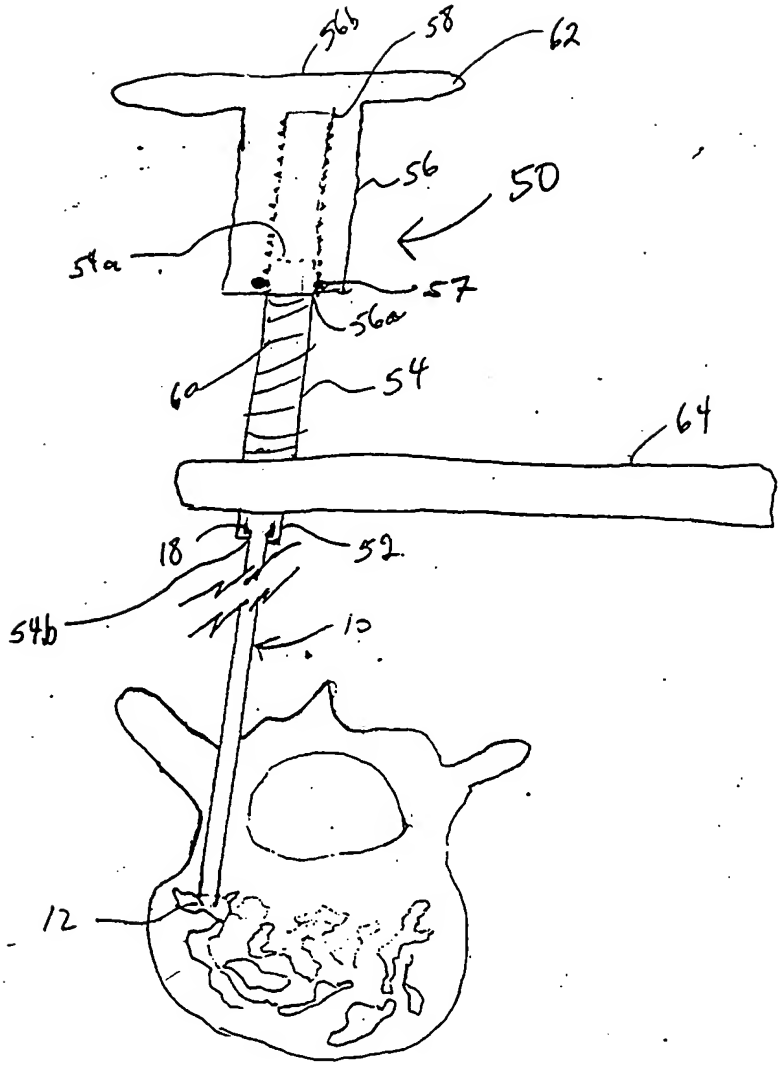

Fig. 6

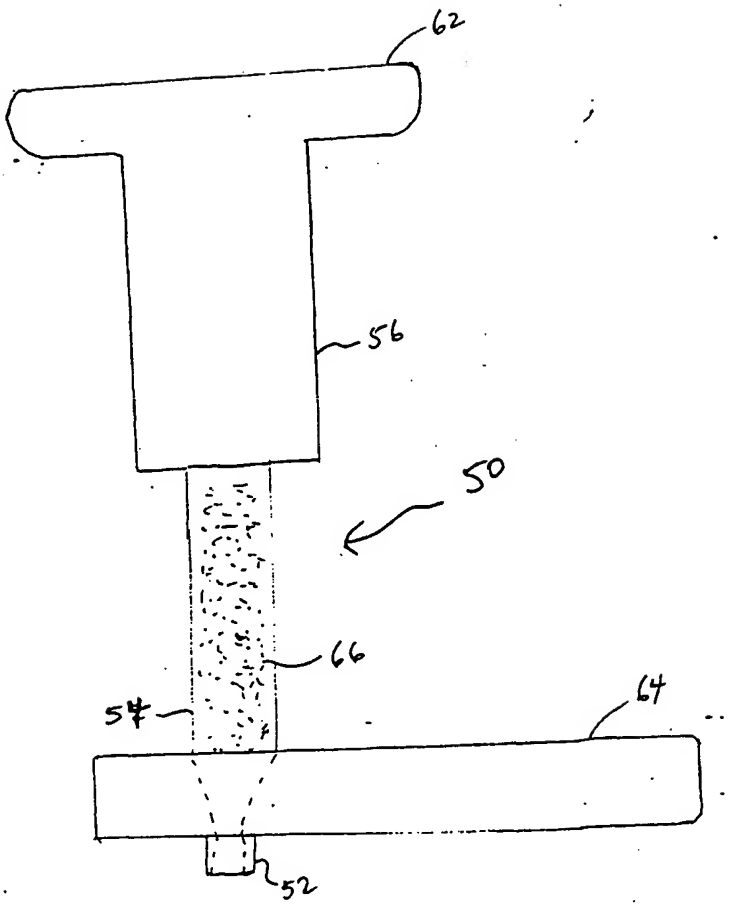

Fig. 7

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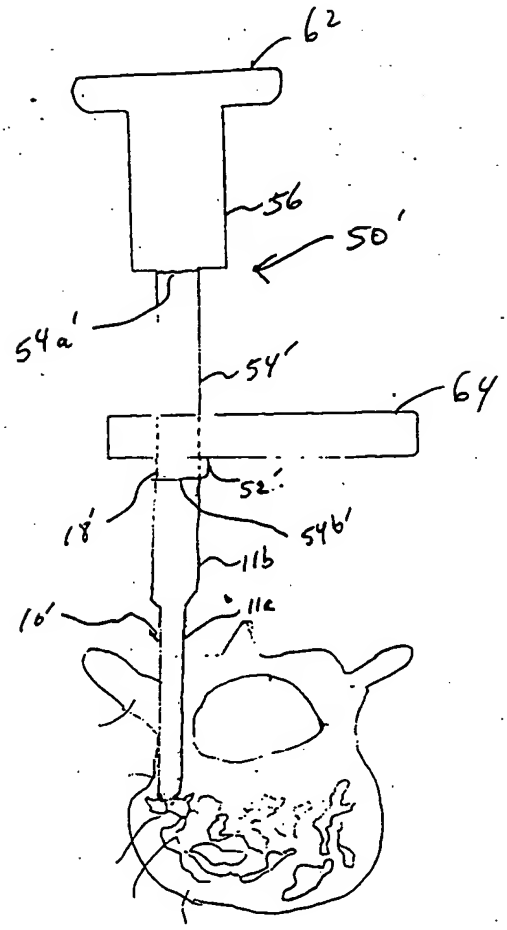

Fig. 8

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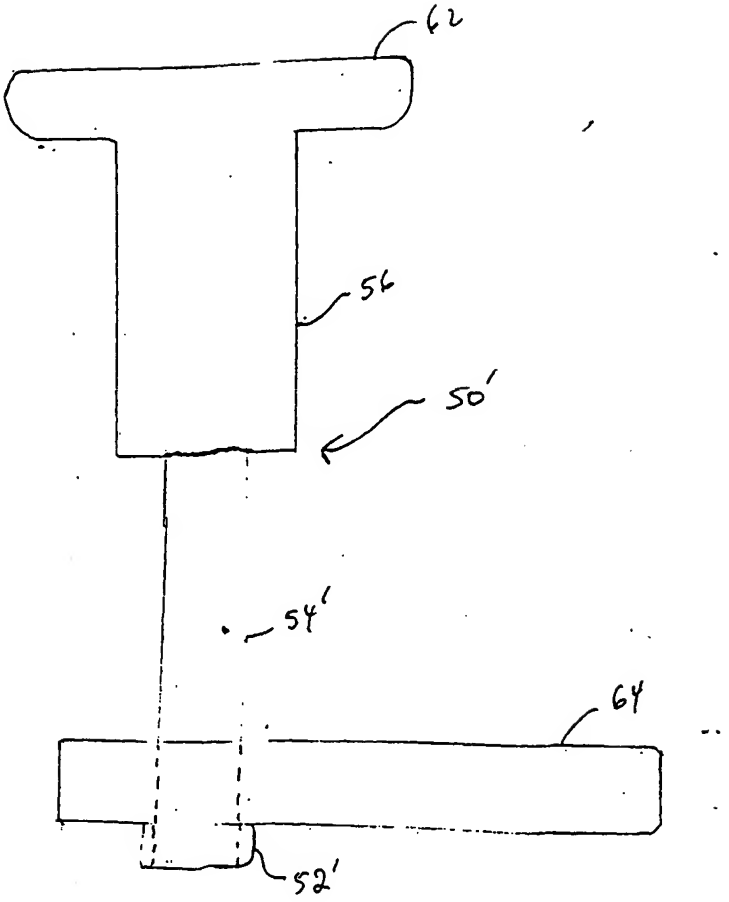

Fig. 9

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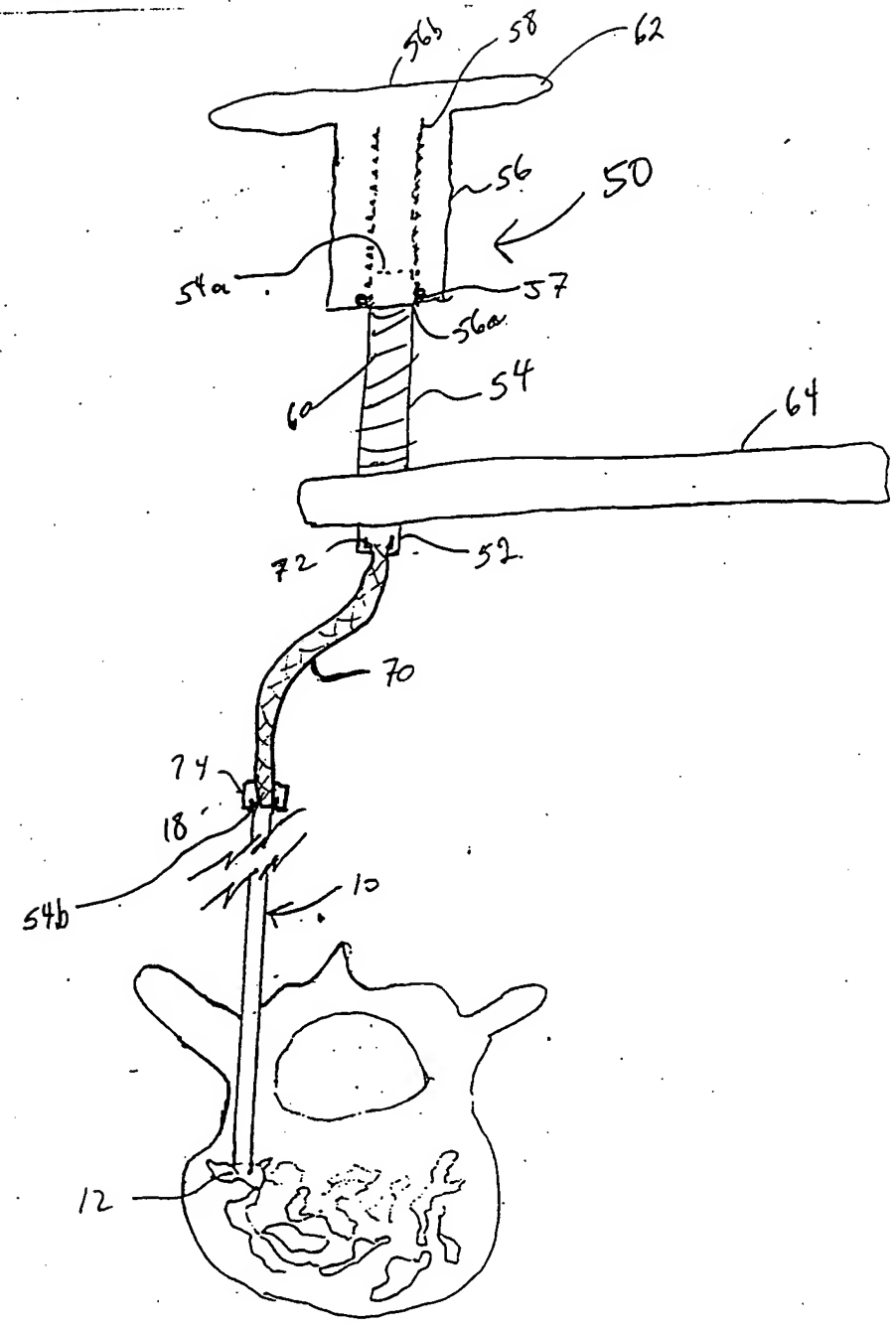

Fig. 10

1111 8

PATENT APPLICATION FEE DETERMINATION RECORD

Effective October 1, 1997

Application or Docket Number

CLAIMS AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY TYPE [ ] RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
BASIC FEE				395.00	OR		790.00
TOTAL CLAIMS	30 minus 20 =	* 10	x$11=		OR	x$22=	220.00
INDEPENDENT CLAIMS	4 minus 3 =	* 1	x41=		OR	x82=	82.00
MULTIPLE DEPENDENT CLAIM PRESENT			+135=		OR	+270=	
			TOTAL		OR	TOTAL	1092.00

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
x$11=		OR	x$22=	
x41=		OR	x82=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
x$11=		OR	x$22=	
x41=		OR	x82=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
x$11=		OR	x$22=	
x41=		OR	x82=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/053,108	04/01/98	PREISSMAN	36172/00000

02/22/0505

ALAN W. CANNON
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO CA 94304-1018

NOT ASSIGNED

3731

DATE MAILED: 05/05/98

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). **If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☒ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.**

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☒ non-small entity is $ 828.

☑ 1. The statutory basic filing fee is:
- ☑ missing.
- ☐ insufficient.

Applicant must submit $ 790 *to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).*

☑ 2. Additional claim fees of $_____, including any multiple dependent claim fees, are required.

$ 82 for 1 independent claims over 3.

$ 220 for 30 dependent claims over 20.

$_____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☑ 3. The oath or declaration:
- ☑ is missing or unexecuted.
- ☐ does not cover the newly submitted items.
- ☐ does not identify the application to which it applies.
- ☐ does not include the city and state or foreign country of applicant's residence.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application does not comply with the Sequence Rules.
See attached "Notice to Comply with Sequence Rules 37 CFR 1.821-1.825."

☐ 9. OTHER: _____

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY

FORM PTO-1533 (REV.9-97)

Sector 41

PATENT
Docket No. 361722000300

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on July 2, 1998.

Michelle Fissel

Michelle Fissel

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Howard Preissman

Serial No.: 09/053,108

Filing Date: April 1, 1998

For: PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT

Examiner: Not Yet Assigned

Group Art Unit: 3731

TRANSMITTAL LETTER FOR MISSING PARTS OF APPLICATION

Box Missing Parts
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In complete response to the Notice to File Missing Parts of Application Under 37 C.F.R. § 1.53(d) dated May 5, 1998, attached please find:

- ☒ A copy of the Notice to File Missing Parts of Application FORM PTO-1533 (1 page).
- ☒ A declaration signed by the inventor and the surcharge of $65.00 as set forth in 37 C.F.R. § 1.16(e) (2 pages).
- ☒ A Power of Attorney and Prosecution by Assignee Under 37 C.F.R. § 3.71 (2 pages).
- ☒ A Declaration of Small Entity Status (1 page).
- ☒ Certificate Under 37 C.F.R. § 3.73 (b) with attached copy of assignment and Notary Acknowlegment (3 pages)
- ☒ Other: Return receipt postcard.

The filing fee has been calculated as follows:

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
TOTAL CLAIMS	30 - 20 =	-10-	x $22.00	$220.00
INDEPENDENT CLAIMS	4 - 3 =	-1-	x $82.00	$82.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $270.00	$0.00
[redacted]			BASIC FEE	$790.00
[redacted]		TOTAL OF ABOVE CALCULATIONS =		$1092.00
SURCHARGE FOR FILING MISSING PARTS				$130.00
Reduction by 1/2 for filing by small entity (Note 37 C.F.R. §§ 1.9, 1.27, 1.28). If applicable, verified statement must be attached.				$611.00
[redacted]			TOTAL =	$611.00

☒ A check in the amount of $611.00 is attached.

The Assistant Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this transmittal and associated documents, or to credit any overpayment to **Deposit Account No. 03-1952**. A duplicate copy of this transmittal is enclosed for that purpose.

Respectfully submitted,

Dated: July 2, 1998

By: _____
Alan W. Cannon
Registration No. 34,977

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5722
Facsimile: (650) 494-0792

PTO/SB/96 (10-92)

CERTIFICATE UNDER 37 C.F.R. § 3.73(b)	Docket No. 361722000300

In the application of:	H9/053,108
Serial No.:	A09/053,108
Filed:	April 1, 1998
For:	PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT

Parallax Medical, Inc., a corporation certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application identified above, for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s) of the patent application identified above, to the current assignee as shown below:

1. From : *
   To: *
   The document was recorded in the Patent and Trademark Office at Reel *, Frame *, or for which a copy thereof is attached.

2. From : *
   To: *
   The document was recorded in the Patent and Trademark Office at Reel *, Frame *, or for which a copy thereof is attached.

3. From : *
   To: *
   The document was recorded in the Patent and Trademark Office at Reel *, Frame *, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ Copies of assignments or other documents in the chain of title are attached.

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned (whose title is supplied below) is empowered to sign this certificate on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 6/9/98

Name: Howard Preissman
Title: President and CEO

COPY

Attorney Docket No.: 361722000300

ASSIGNMENT
SOLE

THIS ASSIGNMENT, by Howard Preissman (hereinafter referred to as the assignor), residing at 2140 Jonathon Avenue, San Jose, California 95125 respectively, witnesseth:

WHEREAS, said assignor has invented certain new and useful improvements in PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT, set forth in an application for Letters Patent of the United States, bearing Serial No. 09/053,108 and filed on April 1, 1998; and

WHEREAS, Parallax Medical, Inc., a corporation duly organized under and pursuant to the laws of California and having its principal place of business at 2140 Jonathon Avenue, San Jose, California 95125 (hereinafter referred to as the assignee) is desirous of acquiring the entire right, title and interest in and to said inventions and said application for Letters Patent of the United States, and in and to any Letters Patent or Patents, United States or foreign, to be obtained therefor and thereon:

NOW, THEREFORE, in consideration of One Dollar ($1.00) and other good and sufficient considerations, the receipt of which is hereby acknowledged, said assignor have sold, assigned, transferred and set over, and by these presents does sell, assign, transfer and set over, unto said assignee, its successors, legal representatives and assigns, the entire right, title and interest in and to the above-mentioned inventions, application for Letters Patent, and any and all Letters Patent or Patents in the United States of America and all foreign countries which may be granted therefor and thereon, and in and to any and all divisions, continuations and continuations-in-part of said application, or reissues or extensions of said Letters Patent or Patents, and all rights under the International Convention for the Protection of Industrial Property, the same to be held and enjoyed by said assignee, for its own use and the use of its successors, legal representatives and assigns, to the full end of the term or terms for which Letters Patent or Patents may be granted, as fully and entirely as the same would have been held and enjoyed by the assignor, had this sale and assignment not been made.

AND for the same consideration, said assignor hereby covenant and agree to and with said assignee its successors, legal representatives and assigns, that, at the time of execution and delivery of these presents, said assignor are the sole and lawful owners of the entire right, title and interest in and to said inventions and the application for Letters Patent above-mentioned, and that the same are unencumbered and that said assignors have good and full right and lawful authority to sell and convey the same in the manner herein set forth.

AND for the same consideration, said assignor hereby covenant and agree to and with said assignee, its successors, legal representatives and assigns, that said assignors will, whenever counsel of said assignee, or the counsel of its successors, legal representatives and assigns, shall advise that any proceeding in connection with said inventions, or said application for Letters Patent, or any proceeding in connection with Letters Patent for said inventions in any country, including interference proceedings, is lawful and desirable, or that any division, continuation or continuation-in-part of any application for Letters Patent or any reissue or extension of any Letters Patent, to be obtained thereon, is lawful and desirable, sign all papers and documents, take all lawful oaths, and do all acts necessary or required to be done for the procurement, maintenance, enforcement and defense of Letters Patent for said inventions, without charge to said assignee, its successors, legal representatives and assigns, but at the cost and expense of said assignee, its successors, legal representatives and assigns.

AND said assignor hereby request the Commissioner of Patents to issue said Letters Patent of the United States to said assignee as the assignee of said inventions and the Letters Patent to be issued thereon for the sole use of said assignee, its successors, legal representatives and assigns.

June 10, 1998
Date

Howard Preissman

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

State of California

County of Santa Clara

On June 10, 1998 (Date) before me, Cheryl L. Whiteside Notary Public (Name and Title of Officer (e.g., "Jane Doe, Notary Public"))

personally appeared Howard E. Preissman (Name(s) of Signer(s))

~~☐ personally known to me~~

☒ proved to me on the basis of satisfactory evidence

to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

CHERYL L. WHITESIDE
Comm. # 1150750
NOTARY PUBLIC - CALIFORNIA
Santa Clara County
My Comm. Expires Sept. 6, 2001

WITNESS my hand and official seal.

Cheryl L. Whiteside
Signature of Notary Public

OPTIONAL

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Description of Attached Document

Title or Type of Document: Assignment Sole

Document Date: 6-10-98 Number of Pages: _____

Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____	Signer's Name: _____
☐ Individual	☐ Individual
☐ Corporate Officer Title(s): _____	☐ Corporate Officer Title(s): _____
☐ Partner — ☐ Limited ☐ General	☐ Partner — ☐ Limited ☐ General
☐ Attorney-in-Fact	☐ Attorney-in-Fact
☐ Trustee	☐ Trustee
☐ Guardian or Conservator	☐ Guardian or Conservator
☐ Other: _____	☐ Other: _____
Signer Is Representing:	Signer Is Representing:
RIGHT THUMBPRINT OF SIGNER Top of thumb here	RIGHT THUMBPRINT OF SIGNER Top of thumb here

PATENT
Docket No. 361722000300

DECLARATION FOR UTILITY PATENT APPLICATION

AS A BELOW-NAMED INVENTOR, I HEREBY DECLARE THAT:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT, the specification of which is attached hereto unless the following box is checked:

☒ was filed on April 1, 1998 as United States Application Serial No. 09/053,108.

I HEREBY STATE THAT I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE.

I acknowledge the duty to disclose information which is material to the patentability as defined in 37 C.F.R. § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed:

Application No.	Country	Date of Filing (day/month/year)	Priority Claimed?
			☐Yes ☐No

I hereby claim benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application Serial No.	Filing Date

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this

application.

Application Serial No.	Filing Date	Status
		☐Patented ☐Pending ☐Abandoned

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

6/9/98
Date

Name: Howard Preissman
Residence: 2140 Jonathan Avenue, San Jose, California 95125
Citizenship: USA
Post Office Address: Same as Residence

Applicant/Patentee: Howard Preissman
Serial No./Patent No.: 09/053,108
Filed on/Issued : April 1, 1998
For: PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT

Docket No.: 361722000300

VERIFIED STATEMENT CLAIMING SMALLENTITY STATUS
37 C.F.R. §§ 1.9(f) AND 1.27(c) — SMALL BUSINESS CONCERN

I hereby declare that I am

☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: Parallax Medical, Inc.

ADDRESS OF CONCERN: 2140 Jonathon Avenue, San Jose, CA 95125

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. § 121.12, and reproduced in 37 C.F.R. § 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT by inventor Howard Preissman, described in

☐ the specification filed herewith with title as listed above.
☒ the application identified above.
☐ the patent identified above.

If the rights held by the above identified business concern are not exclusive, each individual, concern or organization having rights in the invention must file separate verified statements averring to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 C.F.R. § 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 C.F.R. § 1.9(d), or a nonprofit organization under 37 C.F.R. § 1.9(e).

Each person, concern or organization having any rights in the invention is listed below:

☐ no such person, concern, or organization exists.
☐ each such person, concern or organization is listed below.

	ADDRESS	TYPE
		☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. § 1.27)

I acknowledge the duty to file, in this application or patent, notification or any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. § 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Howard Preissman
TITLE OF PERSON IF OTHER THAN OWNER: President and CEO
ADDRESS OF PERSON SIGNING: 2140 Jonathon Avenue, San Jose, CA 95125

SIGNATURE: _____ DATE: 6/9/98

PTO/SB/10 (10-92)
pa-276369

PATENT
Docket No. 361722000300

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on July 2, 1998.

Michelle Fissel

Michelle Fissel

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Howard Preissman

Serial No.: 09/053,108

Filing Date: April 1, 1998

For: PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT

Examiner: Not Yet Assigned

Group Art Unit: 3731

PROSECUTION BY ASSIGNEE AND POWER OF ATTORNEY UNDER 37 C.F.R. § 3.71

Box Missing Parts
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Parallax Medical, Inc., the assignee of the entire right, title and interest in this patent application, under 37 C.F.R. § 3.71 hereby appoints:

Thomas E. Ciotti (Reg No. 21,013)
Gladys H. Monroy (Reg No. 32,430)
Stacey J. Farmer (Reg No. P-42,526)
Freddie K. Park (Reg No. 35,636)
Shmuel Livnat (Reg No. 33,949)
Antoinette F. Konski (Reg No. 34,202)
David C. Lundmark (Reg No. P-42,815)
Robert Saltzberg (Reg No. 36,910)
Mani Adeli (Reg No. 39,585)
Sean Brennan (Reg No. 39,917)
Robert K. Cerpa (Reg No. 39,933)
Kate H. Murashige (Reg No. 29,959)
Debra A. Shetka (Reg No. 33,309)
E. Thomas Wheelock (Reg No. 28,825)
Susan K. Lehnhardt (Reg No. 33,943)
Tyler Dylan (Reg No. 37,612)
Harry J. Macey (Reg No. 32,818)
David L. Bradfute (Reg No. 39,117)
Laurie A. Axford (Reg No. 35,053)
Catherine M. Polizzi (Reg No. 40,130)
J. Michael Schiff (Reg No. 40,253)
Ronald D. Devore (Reg No. 39,958)

Lee K. Tan (Reg No. 39,447)
Madeline I. Johnston (Reg No. 36,174)
Stephen C. Durant (Reg No. 31,506)
Hector Gallegos (Reg No. 40,614)
Charles D. Holland (Reg No. 35,196)
Michael Hetherington (Reg No. 32,357)
Thomas D. Mays (Reg No. 34,524)
Wen Liu (Reg No. 32,822)
Cindy S. Kaplan (Reg No. 40,043)
Alan W. Cannon (Reg No. 34,977)
Dahna S. Pasternak (Reg No. 41,411)
Frank Wu (Reg No. 41,386)
Barry E. Bretschneider (Reg No. 28,055)
Mark R. Carter (Reg No. 39,131)
Edward V. Donahue (Reg No. 35,492)
Thomas G. Wiseman (Reg No. 35,046)
Ararat Kapouytian (Reg No. 40,044)

all of Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, California 94304-1018, telephone (650) 813-5600, to prosecute this application and transact all matters in the United States Patent and Trademark Office connected therewith, said appointment to be to the exclusion of the inventors and their attorneys in accordance with the provisions of 37 C.F.R. § 3.71.

Please direct all written communications relative to this application to:

Alan W. Cannon
Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018

Please direct all telephone communications to Alan W. Cannon at (650) 813-5722.

Parallax Medical, Inc.
a California corporation

Dated: 6/9, 1998

Name: Howard Preissman
Title: President and CEO
Address: 2140 Jonathon Avenue
San Jose, CA 95125

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/053,108	04/01/98	PREISSMAN	H 361722000300

0222/0505

ALAN W. CANNON
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO CA 94304-1018

NOT ASSIGNED

3731

DATE MAILED: 05/05/98

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). If any of items 1 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☒ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.

If all required items identified in this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (or ☒ non-small entity) is $ 990.

☒ 1. The statutory basic filing fee is:
☐ missing.
☐ insufficient.
Applicant must submit $ 190 to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

Additional claim fees of $ _____, including any multiple dependent claim fees, are required.

02/07/1998 GNUGYEN 00000097 09053108
01 FC:201 $ 80.00 DP 4 independent claims over 3.
02 FC:202 $ 220 for 30 dependent claims over 20.
03 FC:203 $ 390.00 DP for multiple dependent claim surcharge.
04 FC:205 $ 65.00 DP
Applicant must either submit additional claim fees or cancel additional claims for which fees are due.

☒ 3. The oath or declaration:
☒ is missing or unexecuted.
☐ does not cover the newly submitted items.
☐ does not identify the application to which it applies.
☐ does not include the city and state or foreign country of applicant's residence.
An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____
An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).
☐ 7. Your filing receipt was mailed in error because your check was returned without payment.
☐ 8. The application does not comply with the Sequence Rules.
See attached "Notice to Comply with Sequence Rules 37 CFR 1.821-1.825."
☐ 9. OTHER: _____

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the reply.

Teresa Dixon
Customer Service Center
Initial Patent Examination Division (703) 308-1202

Missing Pt - 6A
RLL
5/5/98
12/5/98 - F1

PART 2 - COPY TO BE RETURNED WITH RESPONSE

FORM PTO-1533 (REV.9-97)

GAU 3731
9.5.98
5/IDS

PATENT
Docket No. 361722000300

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on July 2, 1998.

Jean Gillespie

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Howard Preissman

Serial No.: 09/053,108

Filing Date: April 1, 1998

For: PRESSURE APPLICATOR FOR HARD TISSUE IMPLANT PLACEMENT

Examiner: Unknown

Group Art Unit: 3731

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted:

☒ Within three months of the application filing date or before receipt of a first Office Action on the merits; accordingly, no fee or separate requirements are required.

☐ After receipt of a first Office Action on the merits but before a final Office Action or Notice of Allowance.

- ☐ A fee is required. An authorization to charge the deposit account is provided below.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.

☐ After receipt of a final Office Action or Notice of Allowance, but before payment of the issue fee. Accordingly, a Petition requesting consideration of the Information Disclosure Statement, an authorization to charge our deposit account, and a Certification under 37 C.F.R. § 1.97(e) are provided herein.

The Assistant Commissioner is hereby authorized to charge any fees which may be required by this statement to **Deposit Account Number 03-1952.**

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

This Information Disclosure Statement under 37 C.F.R. § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the

like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Dated: July 2, 1998

Respectfully submitted,

By: _____

Alan W. Cannon
Registration No. 34,977

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5722
Facsimile: (650) 494-0792

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]	[illegible]	[illegible]	36172200030

QM31/0413

ALAN W. CANNON
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO CA 94304-1018

EXAMINER	
REIF,D	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 04/13/99

#6

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/053,108	Preissman
Examiner	**Group Art Unit**
David O. Reip	3731

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-30* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 3, 5-12, and 15-30* is/are rejected.

☒ Claim(s) *2, 4, 13, and 14* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: There is no "Brief Description of the Drawings" entry for Figure 10.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

With respect to claims 3 and 5-8, the specification discloses, in a preferred embodiment of the device best seen in Fig. 6, an applicator device comprising an interiorly threaded, closed handle which is threaded over an open end of an exteriorly threaded tube or "column" cement ejector. Pressures of up to 3000 psi are supposedly generated by screwing the handle down onto the tube, with the pressure seal being an O-ring 57 which is shown in Fig. 6 as being placed at the

interface between the interiorly threaded handle body 56 and the exteriorly threaded tube 54. From this examiner's viewpoint, this is an inoperative mode of sealing the instant invention, especially at the high pressures being claimed, because an O-ring is being applied over a threaded surface. Such a configuration will not provide an adequate seal for pressures up to 3000 psi, and would almost certainly result in destruction of the O-ring. While it may be possible that the inventor has designed some proprietary means for making the disclosed seal design work, one of ordinary skill in the art would not be able to make the instant invention without undue experimentation.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4 and 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, lines 5 and 8, the limitation "the other end" lacks antecedent basis in the claim.

With respect to claims 10-12, it is unclear how the method can be practiced as claimed, since it would most certainly be extremely harmful to a patient to apply the implant material to an implant site in a bone within the pressure range of 1000-3000 psi. It is obvious that such high

pressures could not be sustained after the implant site was effectively filled with the implant material without causing an explosive failure of the bone. Therefore, the applicant must substantially clarify the method to include how such high pressures are applied and for what duration during the filling of the implant site can such high pressures be sustained before the pressure must be released, etc.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 5-8 rejected under 35 U.S.C. 102(b) as being anticipated by Irving (U.S. Pat. No. 29,083). Fig. 1-3 show an applicator device which could be used to deliver hard tissue implant material, the device having all the limitations as recited in claims 5-8, including a chamber B and means (b, C) for manually applying pressure to the chamber, and a stabilizer D fixedly attached to a portion of the chamber. Note that with respect to the 1000-3000 psi pressure range claimed, this examiner sees the threaded structure of the device as inherently capable of providing the high pressures as claimed.

8. Claims 9 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Dozier, Jr (U.S. Pat. No. 4,815,454). Figs. 3-5 and the disclosure in col. 6, line 39 through col. 7, line 38 of Dozier, Jr. show a bone cement application method which is substantially as claimed.

With respect to claim 9, the above cited figures and disclosure shows inserting a delivery tube 26, connecting a "high" pressure applicator 31 to the delivery tube, and applying a high pressure to the implant material to drive the implant material through the delivery tube and into the site. It is noted that the term "high" is relative, and that any selected pressure can be said to be "high" pressure.

With respect to claim 19, Fig. 5 shows connecting the applicator directly to the delivery tube, when considering nozzle 22 as part of the applicator.

With respect to claim 20, Fig. 5 alternatively shows connecting the applicator to a "high" pressure tube 22 and in turn connecting the tube 22 to the delivery tube 26.

With respect to claim 21, it can be said that plug 25 comprises the "delivery tube" and expander 26 comprises the "high pressure tube", and therefore Figs. 4 and 5 show connecting the high pressure applicator 22 to the high pressure tube 26, which has been connected to the delivery tube 25.

9. Claims 22-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Tronzo (U.S. Pat. No. 4,653,489). Fig. 1 of Tronzo shows a system for implanting hard tissue material having all the limitations as recited in claims 22 and 24-30

With respect to claim 22, Fig. 1 shows an applicator 50, a delivery tube 32, and means 46 for interconnecting the applicator and the delivery tube.

With respect to claim 23, the term "Luer lock" has been significantly broadened in the art to include connectors having various structures, including having complementary tapered, straight and/or threaded surfaces. Therefore, this examiner sees (in Fig. 1) both the connection 48 between the tube 46 and delivery tube 32 as well as the connection between the tube 46 and the end of the applicator 50 could be called "Luer lock" connectors.

With respect to claim 24, Fig. 1 shows a portion of "high" pressure tubing 46 connected to "pressure" fittings on the delivery tube and the applicator.

With respect to claim 25, Fig. 1 shows insertable "stylet" 14 which serves to guide the insertion of the delivery tube 32.

With respect to claims 26-29, the 20 cc applicator 50 (see col. 4, lines 1-2) comprises a reservoir for containing the implant material, is defined by a pair of interfitting cylindrical portions, and has "stabilizers" (the radially extending flanges on the syringe body and plunger) fixedly attached.

With respect to claim 30, this examiner sees the applicator 50 as having being *structurally capable* of generating pressures up to about 3000 psi, given the application of a sufficient amount of force to the plunger of the applicator.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dozier, Jr..

13.As previously discussed, Dozier, Jr. shows a method of implantation which is basically the same as that recited in claims 15-18. However, Dozier, Jr. does not specifically disclose using a fluoroscope as an aid in implanting the delivery tube and viewing the delivery of the implant material. Use of imaging devices, including fluoroscopes, during surgery as an aid to the surgeon is a well known practice. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a fluoroscope while performing the claimed method, since using an imaging device during a surgical procedure increases the accuracy and safety of the operation.

Allowable Subject Matter

14. Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

15. Claims 10-12 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. Claims 2, 4, 13 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. German patent DE3443167 is cited as a bone cement applicator having a stabilizer handle on the applicator chamber and screwed-in plunger mechanism which would be capable of applying high pressures to the cement chamber.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip at (703) 308-3383. The examiner can normally be reached Mon-Thu and every other Fri from 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Buiz, can be reached at (703) 308-0871. The fax number for this Unit is (703) 308-2708 (unofficial) or (703) 305-3590 (official).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at (703) 308-0858.

David O. Reip
Assistant Examiner
April 8, 1999

MICHAEL BUIZ
SUPERVISORY PATENT EXAMINER
GROUP 3300
4/8/99

Notice of References Cited

Application No.	Applicant(s)		
09/053,108	Preissman		
Examiner		Group Art Unit	Page 1 of 1
David O. Reip		3731	

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	4,653,489	3/31/87	Tronzo	606	65
B	29,083	7/10/60	Irving	604	224
C					
D					
E					
F					
G					
H					
I					
J					
K					
L					
M					

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
N	DE3443167	5/6/86	Germany	Orthoplant	--	--
O						
P						
Q						
R						
S						
T						

NON-PATENT DOCUMENTS

	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
U		
V		
W		
X		

Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 361722000300	Application Number 09/053,108
Applicant: Howard Preissman	
Filing Date April 1, 1998	Group Art Unit 3731

RECEIVED
JUL 10 1998
GROUP 3200

OIPE JUL 06 1998 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
DR	1.	06/23/81	4,274,163	Malcolm et al.	606	94	
DR	2.	06/09/87	4,671,263	Draenert	606	94	
DR	3.	03/28/89	4,815,454	Dozier, Jr.	606	94	
DR	4.	05/29/90	4,929,238	Baum	604	208	
DR	5.	05/14/91	5,014,717	Lohrmann	600	567	
DR	6.	09/13/94	5,346,495	Vargas, III	606	92	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES	Translation NO

OTHER DOCUMENTS*(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
DR	7.	Cotten et al., "Preoperative percutaneous injection of methyl methacrylate and N-butyl cyanoacrylate in vertebral hemangiomas" *AJNR* (1996) 17:137-142. 1/96
DR	8.	Cybulski, "Methods of surgical stabilization for metastatic disease of the spine" *Neurosurgery* (1989) 25:240-252. 8/89
DR	9.	Deramond, "Percutaneous vertebroplasty with methyl-methacrylate:Technique, method, results" Space 269. 8/89
DR	10.	Harrington, "Anterior decompression and stabilization of the spine as a treatment for vertebral collapse and spinal cord compression from metastatic malignancy" *Clin. Orthopaedics and Related Research* ~~(1986)~~ pp. 177-197. 8/88
DR	11.	Sundaresen et al., "Treatment of neoplastic epidural cord compression by vertebral body resection and stabilization" *J. Neurosurg.* (1985) 63:676-684. 11/85
	12.	Well et al., "Spinal metastases: Indications for and results of percutaneous injection of acrylic surgical cement" *Radiology* (1996) 199:241-247. 4/96

EXAMINER: (examiner) David O. Reif DATE CONSIDERED: 4/7/99

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

FORM PTO 948 (REV. 11-97) U.S. DEPARTMENT OF COMMERCE-Patent and Trademark Office Application No. 09/053108

NOTICE OF DRAFTPERSON'S PATENT DRAWING REVIEW

The drawing filed (insert date) 04/01/98 are:

A. ____ not objected to by the Draftperson under 37 CFR 1.84 or 1.152.

B. ✓ objected to by the Draftperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings whe necessary. Corrected drawings must be submitted according to the instructions on the back of this notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color.
   - ____ Color drawing are not acceptable until petition is granted. Fig.(s) ____
   - ____ Pencil and non black ink is not permitted. Fig(s)____

2. PHOTOGRAPHS. 37 CFR 1.84(b)
   - ____ Photographs are not acceptable until petition is granted.
   - ____ 3 full-tone sets are required. Fig(s)____
   - ____ Photographs not properly mounted (must brystol board or photographic double-weight paper). Fig(s)____
   - ____ Poor quality (half-tone). Fig(s)____

3. TYPE OF PAPER. 37 CFR 1.84(e)
   - ____ Paper not flexible, strong, white and durable. Fig.(s)____
   - ✓ Erasures, alterations, overwritings, interlineations, folds, copy machine marks not acceptable. (too thin)
   - ____ Mylar, vellum paper is not acceptable (too thin). Fig(s)____

4. SIZE OF PAPER. 37 CFR 1.84(F): Acceptable sizes:
   - ____ 21.0 cm by 29.7 cm (DIN size A4)
   - ____ 21.6 cm by 27.9 cm (8 1/2 x 11 inches)
   - ____ All drawings sheets not the same size. Sheet(s)____

5. MARGINS. 37 CFR 18.4(g): Acceptable margins:
   - Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: A4 Size
   - Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: 8 1/2 x 11
   - ____ Margins not acceptable. Fig(s)____
   - ____ Top (T) ____ Left (L)
   - ____ Right (R) ____ Bottom (B)

6. VIEWS. CFR 1.84(h)
   REMINDER: Specification may require revision to correspond to drawing changes.
   - ____ Views connected by projection lines or lead lines. Fig.(s)____

   Partial views. 37 CFR 1.84(h)(2)
   - ____ Brackets needed to show figure as one entity. Fig.(s)____
   - ____ Views not labeled separately or properly. Fig.(s)____
   - ____ Enlarged view not labeled separately or properly. Fig (s)____

7. SECTIONAL VIEWS. 37 CFR 1.84(h)(3)
   - ____ Hatching not indicated for sectional portions of an object. Fig.(s)____
   - ____ Sectional designation, should be noted with Arabic or Roman numbers. Fig.(s)____

8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   - ____ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned, so that the top becomes the right side, except for graphs. Fig.(s)____
   - ____ Views not on the same plane on drawing sheet. Fig.(s)____

9. SCALE. 37 CFR 1.84(k)
   - ____ Scale not large enough to show mechansim without crowding when drawing is reduced in size to two-thirds in reproduction. Fig.(s)____

10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)
   - ✓ Lines, numbers & letters not uniformly thick and well defined, clean, durable and black (poor line quality). Fig.(s) 1-10

11. SHADING. 37 CFR 1.84(m)
   - ____ Solid black areas pale. Fig.(s)____
   - ____ Solid black shading not permitted. Fig.(s)____
   - ____ Shade lines, pale, rough and blurred. Fig.(s)

12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
   - ____ Numbers and reference characters not plain and legible. Fig.(s)____
   - ____ Figure legends are poor. Fig.(s)____
   - ____ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(3) Fig.(s)____
   - ____ English alphabet not used. 37 CFR 1.84(p)(3) Fig.(s)____
   - ✓ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig.(s) 1-10

13. LEAD LINES. 37 CFR 1.84(q)
   - ____ Lead lines cross each other. Fig.(s)____
   - ____ Lead lines missing. Fig.(s)____

14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.48(t)
   - ____ Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Fig.(s)____

15. NUMBERING OF VIEWS. 37 CFR 1.84(u)
   - ____ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig.(s)____

16. CORRECTIONS. 37 CFR 1.84(w)
   - ____ Corrections not made from PTO-948 dated ____

17. DESIGN DRAWINGS. 37 CFR 1.152
   - ____ Surface shading shown not appropriate. Fig.(s)____
   - ____ Solid black shading not used for color contrast. Fig.(s)____

COMMENTS

REVIEWER Roderick DATE 07/30/98 TELEPHONE NO. 703 305 8404

ATTACHMENT TO PAPER NO.____

PTO COPY

UNITED STAT DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/053,108	04/01/98	PREISSMAN H	361722000300

QM12/1018

ALAN W. CANNON
MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO CA 94304-1018

EXAMINER	
REIP,D	
ART UNIT	**PAPER NUMBER**
3731	7

DATE MAILED: 10/18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Notice of Abandonment

Application No.	Applic ,s)
09/053,108	Preissman
Examiner: David O. Reip	Group Art Unit: 3731

This application is abandoned in view of:

☒ applicant's failure to timely file a proper response to the Office letter mailed on Apr 13, 1999 .

☐ A response (with a Certificate of Mailing or Transmission of _____) was received on _____, which is after the expiration of the period for response (including a total extension of time of ___ month(s)) which expired on _____ .

☐ A proposed response was received on _____ , but it does not constitute a proper response to the final rejection.

(A proper response to a final rejection consists only of: a timely filed amendment which places the application in condition for allowance; a Notice of Appeal; or the filing of a continuing application under 37 CFR 1.62 (FWC)).

☒ No response has been received. CONFIRMED VIA TELEPHONE CONTACT WITH MR. CANNON. CIP FILED, PARENT CASE ABANDONED.

☐ applicant's failure to timely pay the required issue fee within the statutory period of three months from the mailing date of the Notice of Allowance.

☐ The issue fee (with a Certificate of Mailing or Transmission of _____) was received on _____ .

☐ The submitted issue fee of $_____ is insufficient. The issue fee required by 37 CFR 1.18 is $_____ .

☐ The issue fee has not been received.

☐ applicant's failure to timely file new formal drawings as required in the Notice of Allowability.

☐ Proposed new formal drawings (with a Certificate of Mailing or Transmission of _____) were received on _____ .

☐ The proposed new formal drawings filed _____ are not acceptable.

☐ No proposed new formal drawings have been received.

☐ the express abandonment under 37 CFR 1.62(g) in favor of the FWC application filed on _____ .

☐ the letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

☐ the letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

☐ the decision by the Board of Patent Appeals and Interferences rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

☐ the reason(s) below:

MICHAEL BUIZ
SUPERVISORY PATENT EXAMINER
GROUP 3300

10/17/99

PTO/SB/68 (04-01)
Approved for use through 10/31/2002. OMB 0651-0031
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR ACCESS TO AN APPLICATION UNDER 37 CFR 1.14(e)

In re Application of	
Application Number: 09/053,108	Filed: 04/01/98
Art Unit	Examiner

RECEIVED
MAR 1 8 2002
File Information Unit

Paper No. #8

Assistant Commissioner for Patents
Washington, DC 20231

1. ☑ I hereby request access under 37 CFR 1.14(e)(2) to the application file record of the above-identified ABANDONED Application, which is not within the file jacket of a pending Continued Prosecution Application (CPA) (37 CFR 1.53(d)) and is: (CHECK ONE)

☑ (A) referred to in:

United States Patent Application Publication No. 6348055, page ____, line ____,

United States Patent Number ____, column 2, line 30, or

an International Application which was filed on or after November 29, 2000 and which designates the United States, WIPO Pub. No. ____, page ____, line ____.

☑ (B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11(b) or 1.14(e)(2)(i), i.e., Application No. ____, paper No. ____, page ____, line ____.

2. ☐ I hereby request access under 37 CFR 1.14(e)(1) to an application in which the applicant has filed an authorization to lay open the complete application to the public.

Kien Vu
Signature

3/18/02
Date

KIEN VU
Typed or printed name

FOR PTO USE ONLY

Approved by: ____

Unit: File Information Unit

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PTO/SB/68 (04-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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REQUEST FOR ACCESS TO AN APPLICATION UNDER 37 CFR 1.14(e)

In re Application of	
Preiss, et al.	
Application Number: 09/053,108	Filed: 4/1/98
Art Unit	Examiner

RECEIVED
JUN 0 3 2002
File Information Unit

Paper No. #9

Assistant Commissioner for Patents
Washington, DC 20231

1. ☒ I hereby request access under 37 CFR 1.14(e)(2) to the application file record of the above-identified ABANDONED Application, which is not within the file jacket of a pending Continued Prosecution Application (CPA) (37 CFR 1.53(d)) and is: (CHECK ONE)

☐ (A) referred to in:

United States Patent Application Publication No. 6,383,190, page ____, line ____,

United States Patent Number ____, column ____, line ____, or

an International Application which was filed on or after November 29, 2000 and which

designates the United States, WIPO Pub. No. ____, page ____, line ____.

☐ (B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11(b) or 1.14(e)(2)(i), i.e., Application No. ____, paper No. ____, page ____, line ____.

2. ☐ I hereby request access under 37 CFR 1.14(e)(1) to an application in which the applicant has filed an authorization to lay open the complete application to the public.

Azieb Tesfay
Signature

6/3/02
Date

Azieb Tesfay
Typed or printed name

FOR PTO USE ONLY

Approved by: ____ (initials) GW

Unit: ____ FLY